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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,760	01/31/2002	James F. McGuckin JR.	10121/02401	2438

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EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

YK

Office Action Summary	Application No. 10/062,760	Applicant(s) MCGUCKIN ET AL.	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2002 and 08 July 2003 and 02 Dec .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 7, 8 and 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 5, 6</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: ~~36~~, 42, 43, ~~63~~, ~~65~~, ~~75~~, 120 and 150. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 16'. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 9-12 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 9 recites the limitation "the row of staples" in lines 2-3 and "the substantially-C-shaped clamp" in line 3. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 16 recites the limitation "the gross adjustment mechanism" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 and 17, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,868,760 to McGuckin, Jr.

Regarding claims 1 and 17, McGuckin discloses a system for stapling tissue comprising: an operative head including a pair of opposed, curved tissue clamping jaws (FIG. 18 and 19) sized to pass through an esophagus (Column 1 lines 58-61), the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration (Column 13 lines 22-40), a first one of the curved jaws including a stapling mechanism (FIG. 23 lip 28) and a second one of the jaws including a staple forming anvil surface (FIG. 24 member 22), the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof (FIG. 19 aperture 108); and a control handle which (operating control module 14), when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator (knob 38) for moving the jaws relative to one another and a second actuator for operating the stapling mechanism (trigger 36).

Regarding claims 2 and 20, McGuckin discloses a tissue cutting mechanism for severing from the patient's body tissue located radially within the row of staples (Column 14 lines 28-63).

Regarding claim 3, McGuckin discloses a staple pusher mounted for movement within the first jaw along a path substantially parallel to the row of staples (FIG. 24 assembly 50).

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Regarding claim 4, McGuckin discloses that the stapling mechanism fires staples in a plurality of substantially parallel rows (FIG. 19).

Regarding claim 5, McGuckin discloses that a tissue cutting mechanism for severing from the patient's body tissue located radially within the row of staples wherein the tissue cutting mechanism comprises a blade coupled to the staple pusher (Column 14 lines 28-63 and Column 18 line 66-Column 19 line 8).

Regarding claim 18, McGuckin discloses that the tissue is located in the patient's stomach and the folds of tissue are coupled to one another (Column 1 lines 58-61).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,403,326 to Harrison et al. in view of U.S. Patent No. 5,389,098 to Tsuruta et al.

Harrison discloses a method for stapling tissue comprising the steps of: inserting into a patient's mouth a flexible endoscope (Column 9 lines 9-14) device including an operative head having a pair of opposed, tissue clamping jaws (jaws 66) , a first one of the jaws including a stapling mechanism (FIG. 8A.) and a second one of the jaws including a staple forming anvil surface (FIG. 8A); moving the jaws relative to one another from a closed position to an open tissue receiving position; drawing a folded, full-thickness portion of tissue from one of the patient's stomach and esophagus between the jaws (FIG. 8A); moving the jaws from the open position to the closed

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position to clamp the tissue between staple slots formed in the first jaw through which staples are fired by the stapling mechanism and the staple forming surface (Column 3 lines 44-55), wherein the staple slots are arranged in a row extending from a proximal end of the first jaw to a distal end thereof (FIG. 8A); and actuating the stapling mechanism to drive staples out of the staple slots through the tissue and against the staple forming surface to couple the folds of tissue to one another (FIG. 8B). Harrison discloses the claimed invention except for the jaws being curved. Tsuruta teaches that it is known in the art to provide curved jaws for stapling the stomach since curved jaws can approximate the curve of the stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Harrison with the curved jaws of Tsuruta in order to approximate the shape of the stomach more accurately.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. '760 in view of U.S. Patent No. 5,582,615 to Foshee et al.

McGuckin discloses the claimed invention except for the operative head further including a second jaw moving mechanism for fine adjustment of the jaws relative to one another. Foshee teaches that a second jaw moving mechanism is necessary to allow the surgeon to incrementally adjust the pressure that is applied to the staple in order to position the staple prior to its final closure (Column 8 line 66-Column 9 line 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of McGuckin with the second jaw moving mechanism in order to be able to position the staple prior to its final placement.

Allowable Subject Matter

12. Claims 7, 8 and 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a second jaw moving mechanism comprising a C-shaped clamp received around the first and second jaws, the second jaw moving mechanism including an I-beam member with a web which extends through corresponding slots in the first and second jaws, and the gross adjustment mechanism comprising a cable extending between the control handle and the operative head.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to similar surgical staplers and related surgical methods:

U.S. Patent No. 5,190,203 to Rodak

U.S. Patent No. 5,392,978 to Velez et al.

U.S. Patent No. 6,506,196 to Laufer

U.S. Patent No. 6,554,271 to Adams et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter

Examiner

Art Unit 3731

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jrb

July 22, 2003

Kevin T. Truong
KEVIN T. TRUONG
PRIMARY EXAMINER

7/24/03